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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/450,136 04/17/00 JENTSCH

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EXAMINER

FORMAN, D.	
ART UNIT	PAPER NUMBER

1655
DATE MAILED:

10

06/27/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/463,136

Applicant(s)

JENTSCH ET AL.

Examiner

BJ Forman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 April 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 18) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

DETAILED ACTION

1. This action is in response to papers filed 25 April 2001 in Paper No. 8 in which claims 1-19 were canceled and claims 20-37 were added. All of the amendments have been thoroughly reviewed and entered. The previous rejections in the Office Action of Paper No. 7 dated 25 October 2000 are withdrawn in view of the amendments. All of the arguments have been thoroughly reviewed but are deemed moot in view of the canceled claims and new grounds of rejection. The previous objection to the Abstract is withdrawn in view of the Abstract filed in Paper No. 8. The previous objection to the Specification is withdrawn in view of the Substitute Specification filed in Paper No. 8. The previous objection to the Drawings is withdrawn in view of the corrected Drawings filed in Paper No. 8.

New grounds for rejection are discussed.

Currently claims 20-37 are under prosecution.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 20-37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claims 20-35 are indefinite in Claim 20 for the preamble recitation "said method using a dispenser.....wherein each of the plurality of ducts includes a portion of the liquid containing the objects" because being in the preamble, it is unclear how the recitation limits the method steps of transporting, positioning, depositing and affixing. It is suggested that Claim 20 be amended to clarify e.g. recite method steps of dispensing.

b. Claims 20-35 are indefinite in Claim 20 for the recitation "outlets are sized to prevent passage of more than one of the objects at a time" because it is unclear whether the outlets prevent passage of more than one object. It is suggested that Claim 20 be amended to clarify e.g. delete "are sized to".

c. Claim 27 is further indefinite for the recitation "affixing by micro-mechanical means the deposited objects to the support" because the syntax is confusing. It is suggested that the claim be amended to clarify.

d. Claim 33 is indefinite in the recitation "detecting nucleotide sequences" because the recitation lacks proper antecedent basis in Claim 32. It is suggested that the claim be amended to provide proper antecedent basis e.g. replace "nucleotide sequences" with "biological-chemical active substance".

e. Claim 33 is indefinite in the recitation "using the deposited objects" because it is unclear how "using" the objects detects nucleotide sequences. It is suggested that the claim be amended to recite positive and active steps for detecting e.g. hybridizing, labeling.

f. Claims 36 is indefinite in line 9 for the recitation "each tube" because the recitation lacks proper antecedent basis in the claim. It is suggested that the claim be amended to provide proper antecedent basis e.g. replace "tube" with "duct".

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 20-24, 26, 27, and 36 are rejected under 35 U.S.C. 102(b) as being anticipated by Balch et al. (U.S. Patent No. 6,083,763, filed 31 December 1997). Claims 20-22, 24, 26 and

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27 are drawn to a method for affixing micro- and/or nano-objects comprising: transporting the objects, positioning outlets, depositing one object, and affixing the object. The recitation in the preamble which reads "said method using a dispenser.....wherein each of the plurality of ducts includes a portion of the liquid containing the objects" is indefinite, as stated above in ¶ 3, because the method does not recite steps of dispensing and therefore it is unclear how the recitation limits the method. The claims are given the broadest reasonable interpretation consistent with the indefinite claim language and specification wherein the micro- and/or nano-objects are defined as "bio-chemical active micro- and/or nano-objects in the form of three-dimensional shaped bodies such as micro-balls and macro-molecules" (specification, page 2, last line-page 3, line2).

Regarding Claim 20, Balch disclose a method for fixing objects (i.e. droplet) contained in a liquid onto a support comprising: transporting the objects in each of a plurality of ducts in the direction of the corresponding outlets until one object emerges from each of the outlets; positioning the outlets adjacent to the support; depositing one object from each of the outlets onto the support; and affixing the deposited objects to the support (Column 12, lines 12-42) wherein the dispenser includes a plurality of conically narrowing ducts having relatively wider inlets and relatively narrower outlets (i.e. ink-jets, Fig. 3) wherein each of the outlets prevent passage of more than one object (i.e. droplet) and wherein each of the plurality of ducts includes a portion of the liquid containing the objects (Column 14, lines 21-38).

Regarding Claim 21, Balch discloses the method wherein said step of transporting includes applying a pressure difference between the inlet and outlet in each of the plurality of ducts (Column 15, lines 38-54).

Regarding Claim 22, Balch discloses the method wherein said positioning, depositing and affixing take place in a simultaneous manner i.e. due to the interaction of the object and the support which occurs upon contact (Column 15, lines 38-67).

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Regarding Claim 23, Balch disclose the method wherein in the objects are positioned on the support prior to said step of affixing to the support i.e. after deposition, a bispecific ligand spatially localizes the micro-droplets (Column 37, lines 9-15).

Regarding Claim 24, Balch discloses the method further comprising covering the support with a chemically reactive layer prior to the steps of depositing and affixing (Column 33, lines 17-23).

Regarding Claim 26, Balch discloses the method wherein the affixing includes photochemically affixing the deposited objects to the support (Column 16, lines 13-19).

Regarding Claim 27, Balch discloses the method wherein the fixing includes affixing by micro-mechanical means i.e. robotic delivery (Column 12, lines 2-12).

Regarding Claim 36, Balch discloses an apparatus for fixing micro and/or nano-objects which are contained in a liquid onto a support, said apparatus comprising: a positing head including at least one depositing cell, said at least one depositing cell including a bundle-like arrangement of conically narrowing ducts having relatively wider inlets and relatively narrower outlets wherein each of the outlets prevent passage of more than one object at a time (i.e. droplet) and each tube capable of containing a portion of the liquid having a plurality of objects; a support; and at least one actuator for causing relative movement between said positioning cell and said support (Column 11, line 32-Column 12, line 12 and Fig. 3).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 25, 28 and 30-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Balch (U.S. Patent No. 6,083,763, filed 31 December 1997) in view of Lough et al. (U.S. Patent No. 5,900,481, filed 6 November 1996).

Regarding Claim 25, Balch teach a method for fixing objects (i.e. droplet) contained in a liquid onto a support comprising: transporting the objects in each of a plurality of ducts in the direction of the corresponding outlets until one object emerges from each of the outlets; positioning the outlets adjacent to the support; depositing one object from each of the outlets onto the support; and affixing the deposited objects to the support (Column 12, lines 12-42) wherein the dispenser includes a plurality of conically narrowing ducts having relatively wider inlets and relatively narrower outlets (i.e. ink-jets, Fig. 3) wherein each of the outlets prevent passage of more than one object (i.e. droplet) and wherein each of the plurality of ducts includes a portion of the liquid containing the objects (Column 14, lines 21-38) but Balch does not teach affixing includes electrostatically affixing the deposited objects. Lough et al. teach fixing objects contained in a liquid onto a support comprising depositing the object and affixing the object wherein the affixing includes electrostatically affixing (Column 4, lines 53-64) and wherein the micro- and/or nano-objects contained in the liquid further comprised beads (Column 3, lines 10-24). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the objects contained in the liquid of Balch to further comprise beads wherein objects within the liquid are attached to bead as taught by Lough et al. for the expected benefit of increasing the surface area of immobilization for the objects as taught by Lough et al. (Column 2, lines 10-15). One skilled in the art would have been further motivated to affix the objects contained in the liquid of Balch electrostatically for the expected benefit of simplicity i.e. affixing the objects to supports having ionic moieties by ionic interaction to thereby eliminate chemical modification of the support and object for covalent affixing as taught by Lough et al. (Column 4, lines 58-61).

Regarding Claim 28, Balch does not teach magnetizing the objects. However, Lough et al. teach fixing the objects wherein the micro- and/or nano-objects contained in the liquid further comprised magnetic beads (Column 3, lines 10-24). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the micro- and/or nano-objects contained in the liquid of Balch to further comprise magnetic beads wherein macromolecules within the liquid are attached to bead as taught by Lough et al. for the expected benefit of increasing the surface area of immobilization for the macromolecules as taught by Lough et al. One skilled in the art would have been further motivated to magnetically affix the micro- and/or nano-objects contained in the liquid for the expected benefit of simplicity of affixing and removal i.e. the bead can be affixed and removed from the support by simple movement of a magnetic field as taught by Lough et al. (Column 4, lines 54-58).

Regarding Claim 30, Balch et al. do not each the objects are charged electrostatically with a same polarity. However, Lough et al. teach the objects are charged electrostatically with a same polarity i.e. the bead is provided with an ionic moiety which associates with an ionic moiety on the support (Column 4, lines 58-61). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the objects of Balch to provide object charged electrostatically with a same polarity for the expected benefit of simplicity i.e. objects charged with a same polarity are affixed to supports having ionic moieties by ionic interaction to thereby eliminate chemical modification of the support and object for covalent affixing as taught by Lough et al. (Column 4, lines 58-61).

Regarding Claim 31, Lough et al. teach the support is charged electrostatically with an opposite polarity relative to the objects (Column 4, lines 58-61). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to the support of Balch to provide an electrostatically charged support for affixing objects having an opposite polarity as taught by Lough et al. expected benefit of simple affixing by providing objects

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charged with a same polarity the objects are affixed to supports having ionic moieties which eliminates chemical modification of the support and object for covalent affixing as taught by Lough et al. (Column 4, lines 58-61).

Regarding Claim 32, Balch teaches the method wherein the objects dispersed in the liquid of one of the plurality of ducts are a first type of biological-chemical active substance; and wherein the objects dispersed in the liquid of another of the plurality of ducts are a second and different type of biological-chemical active substance (Column 15, lines 38-42) but Balch does not teach the objects are coated with the biological-chemical substance. However, Lough et al. teach the similar affixed objects wherein the objects are coated with the biological-chemical substance and wherein the objects are beads (Column 2, lines 10-16). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the objects of Balch which are biological-chemical active substances by coating beads with the biological-chemical active substances as taught by Lough et al. for the expected benefit of providing increased surface area for immobilization of the biological-chemical active substance as taught by Lough et al. (Column 2, lines 10-16).

Regarding Claim 33, Balch teaches the method further comprising detecting nucleotide sequences using the deposited objects (Column 10, lines 52-67).

Regarding Claim 34, Balch teaches the method wherein said detecting comprises applying a test liquid to the deposited objects on the support and evaluating any chemical reactions which occur (Column 10, line 52-Column 11, line 7).

Regarding Claim 35, Balch teaches the method wherein said step of evaluating includes noting any change in color or fluorescent properties (Column 27, lines 11-25).

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8. Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Balch et al. (U.S. Patent No. 6,083,763, filed 31 December 1997) in view of Lough et al. (U.S. Patent No. 5,900,481, filed 6 November 1996) and Gavin et al. (U.S. Patent No. 6,074,609, filed 3 April 1997).

Regarding Claim 29, Balch teach a method for fixing objects (i.e. droplet) contained in a liquid onto a support comprising: transporting the objects in each of a plurality of ducts in the direction of the corresponding outlets until one object emerges from each of the outlets; positioning the outlets adjacent to the support; depositing one object from each of the outlets onto the support; and affixing the deposited objects to the support (Column 12, lines 12-42) wherein the dispenser includes a plurality of conically narrowing ducts having relatively wider inlets and relatively narrower outlets (i.e. ink-jets, Fig. 3) wherein each of the outlets prevent passage of more than one object (i.e. droplet) and wherein each of the plurality of ducts includes a portion of the liquid containing the objects (Column 14, lines 21-38) but Balch does not teach the method wherein the after fixing the objects on the supports they are covered with a layer of gel. However, Gavin et al. teach the similar method wherein objects fixed on the supports are covered with a layer of gel. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the objects contained in the liquid of Balch to further comprise magnetic beads wherein macromolecules within the liquid are attached to bead as taught by Lough et al. for the expected benefit of increasing the surface area of immobilization for the macromolecules as taught by Lough et al. It would have been further obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the gel covering of Gavin et al. to the fixed objects of Balch and Lough et al. for the expected benefit of facilitating transfer of the fixed objects as taught by Gavin et al. (Column 3, lines 13-15).

9. Claim 37 is rejected under 35 U.S.C. 103(a) as being unpatentable over Balch (U.S. Patent No. 6,083,763, filed 31 December 1997).

Regarding Claim 37, Balch teaches an apparatus for fixing micro and/or nano-objects which are contained in a liquid onto a support, said apparatus comprising: a positing head including at least one depositing cell, said at least one depositing cell including a bundle-like arrangement of conically narrowing ducts having relatively wider inlets and relatively narrower outlets wherein each of the outlets prevent passage of more than one object at a time (i.e. droplet) and each tube capable of containing a portion of the liquid having a plurality of objects; a support; and at least one actuator for causing relative movement between said positioning cell and said support (Column 11, line 32-Column 12, line 12, and Fig. 3 and Fig. 4) wherein the support comprises at least one distancing piece firmly affixed and extending outwardly from said support such that said depositing cell and said support are positioned relative to each other at a distance predefined by a length of said distancing piece i.e. the side walls of each reaction chamber (Column 9, lines 14-23 and Fig. 4) but they do not teach said depositing cell comprises the distancing piece. However, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the location of the distance piece extending from the support in the apparatus of Balch wherein each support comprises distancing pieces which control the distance between the single support and the apparatus by placing a distancing piece on the depositing cell of the apparatus which controls the distance between the depositing cell and all supports for the expected benefit of maintaining a uniform distance between the depositing cell and supports while fixing objects onto multiple supports to thereby produce multiple and identical supports.

10. Applicant's amendment which presented new claims 20-37 of broader scope when compared to the originally presented claims (Remarks, page 10, third full paragraph) necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


Conclusion


11. No claim is allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (703) 306-5878. The examiner can normally be reached on 6:45 TO 4:15.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-8724 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


BJ Forman, Ph.D.
June 26, 2001


S. E. Forman
SUPERVISOR
TECHNICAL STAFF